



Zambia Medicines Regulatory Authority

**GUIDELINES ON THE PREPARATION AND SUBMISSION OF DOSSIERS IN COMMON
TECHNICAL DOCUMENT FORMAT**

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ABBREVIATIONS AND ACRONYMS

AMA	
API	Active Pharmaceutical Ingredient
CEP	Certificate of Suitability (Ph. Eur. monograph)
CHMP	Committee for Medicinal Products for Human Use (formally, Committee for Proprietary Medicinal Products).(EU)
CTD	Common Technical Document
EDQM	European Directorate for the Quality of Medicines EU European Union
GCP	Good Clinical Practice
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
ICH	International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
IPD	Individual Patient Data
IPI	Inactive Pharmaceutical Ingredient IT Information technology
MHRA	UK Medicines and Health products Regulatory Authority MS Member State
NMRA	National Medicines Regulatory Authority
pdf	portable document format
PI	Package Insert
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIL	Patient Information Leaflet
PMF	Plasma Master File
SA	South Africa
SADC	Southern African Development Community SmPC Summary of Product Characteristics (European)
TGA	Australian Therapeutic Goods Authority
UK	United Kingdom
US FDA	United States Food and Drug Administration
USA	United States of America
WHO	World Health Organization



INTRODUCTION

Background

The Zambia Medicines Regulatory Authority is mandated under the medicines and allied substances Act No 3 of 2013 of the Laws of Zambia to regulate medicines and allied substances to ensure that all medicines and allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy.

This guideline provides recommendations for applicants preparing a Common Technical Document (CTD) for marketing authorisation of medicines for submission to the Zambia Medicines Regulatory Authority. The guideline is adopted and in line with the Southern African Development Community (SADC) CTD format.

In line with Article 29 of the SADC Protocol on Health, harmonization of medicines regulatory systems was identified as a critical component within the context of public health and access to medicines, to achieve the regional common agenda on health. In 2013, SADC Health Ministers and Ministers Responsible for HIV and AIDS approved the adoption of the ICH CTD to facilitate harmonization in the region.

While the SADC Regional Guidelines for Registration of Medicines provides a minimum standard on technical requirements within the region, in the past, there has been no harmonisation of the organization of the registration documents. Each SADC Member State (MS) had its own requirements for the organization of the technical reports in the submission of applications for registration of human medicines. To avoid the need to generate and compile different registration dossiers, the SADC guideline on which the ZM CTD is based describes a format for the Common Technical Document (CTD) that will be acceptable in all SADC Member State.

The document describes how to organise applications based on the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines on the CTD.

This document provides recommendations on the format and presentation for product dossiers (PDs)/applications for marketing authorisation.

Objectives

These guidelines are intended to:

- Adopt and adapt the SADC CTD in order to have standardised registration requirements with other SADC Member States thereby facilitating harmonization.
- Fully adopt the modular format of the CTD as developed by ICH;
- Assist applicants in the preparation of PDs/applications by providing clear general guidance on the format of these dossiers; and
- Provide guidance on the location of regional information (Module 1) and other general data requirements.
- Provide for mutual recognition of marketing authorisation decisions.

These measures are intended to promote effective and efficient processes for the development of these Product Dossiers and the subsequent assessment procedures.

Rationale for Adopting ICH CTD Format

To ensure that the ZAMRA standards are aligned with global standards, these are based on the International Council on Harmonisation of Technical Requirements for Registration of Human Medicines (ICH) guidelines on CTD format and the World Health Organization (WHO) Guidelines for Registration of multisource (generic) medicines. Adopting the ICH CTD format will assist applicants to prepare registration dossiers in a single format that can be submitted to several



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countries, promote information exchange among the regulators, more efficient assessment, align the region with global standards such as ICH and WHO and ultimately increase availability of medicines to the public. The intended benefits of adopting the ICH CTD format are in-line with the SADC and AU and AMA agenda on regional integration and cooperation.



Scope

The guidelines apply to medicines for human use of both chemical and biological origin and are applicable to both generic (multisource) and new medicines (innovator). The technical content of the documents in the CTD modules is outside the scope of this guidance. This guideline does not indicate the data or studies required; it merely indicates an appropriate format and organisation for the data that have been acquired. The main Registration Guideline and the relevant guidelines (WHO, ICH or EU) as indicated should be consulted.

ORGANISATION OF PRODUCT DOSSIER IN COMMON TECHNICAL DOCUMENT FORMAT

According to the CTD format, each application is a collection of documents, grouped into 5 modules. A document is a set of pages, numbered sequentially and divided from other documents by a tab. a document can be equated to a file for an electronic submission

This guideline provides information on the contents of the *ZAMRA CTD Module 1: Administrative Information*, as Module 1 is region specific. In addition, the ZAMRA regional CTD format describes the format and organisation of the Summaries, Quality, Non-clinical, and Clinical modules (Modules 2 to 5, respectively).

The CTD guidelines, together with the *SADC Registration Guidelines* provide detailed information about the contents of an application. These guidelines apply to applications to register medicines and all related variations. Applicants should not modify the overall organisation of the CTD. If not contained in the bulk of the documentation, any additional data should be included as addenda to the relevant part, together with additional expert comment that may be provided as a supplement to, or incorporated into, the relevant summary, overall summary or overview.

Module 1 - Administrative information and prescribing information

Relevant administrative documentation should be submitted in Module 1 of the CTD dossier. This module should be divided into the relevant sections, as described in Part B of this guideline.

Module 2 - Summary of the dossier

Module 2 of the CTD dossier contains the summaries and overviews for the quality, non-clinical and clinical sections of the dossier (refer to the European *Notice to Applicants*).

The Clinical Overview should include a statement regarding Good Clinical Practice (GCP) compliance.

In cases concerning generic, the Authority may grant exemption from the submission of Non-clinical and Clinical Overviews and Summaries (2.4, 2.5, 2.6 and 2.7). For generics, the following sections should be submitted:

2.1 Table of contents for Module 2

2.2 Introduction

2.3 Quality overall Summary

Module 3 – Quality

Module 3 of the dossier contains the chemical, pharmaceutical and biological data relevant to the application.

Refer to the Registration guideline for the current requirements for this module.

Full reports on biopharmaceutics studies, including methodology and validation data for bioavailability studies, should be included in Module 5.3.1.

Module 4: Non Clinical Study reports



Module 4 of the dossier contains the non-clinical (pharmaco-toxicological) data relevant to the application.



For detailed information and guidance on information for new medicines, the human study reports and related information should be presented in the order described in ICH M4S. Reference should be made to the most current version of the Guidelines

Generally, module 4 is not applicable for generic medicines.

Module 5: Clinical study reports

Module 5 of the dossier contains the clinical data relevant to the application. In most circumstances, the clinical studies included in Module 5 of the dossier will be international studies used to establish the pharmacodynamics, pharmacokinetics, safety and efficacy of the medicine across an international patient population. However, where there is evidence to suggest that the pharmacokinetics or pharmacodynamics of the product may vary across the populations that will use the medicine in Zambia; the sponsor should consider submitting studies relevant to those target populations.

For detailed information and guidance on presentation of information for new medicines, the human study reports and related information should be presented in the order described in ICH M4E guideline



GENERAL INFORMATION FOR APPLICATIONS

Please read together with the Registration guideline.

1 Preparing and organising the Common Technical Document

To facilitate the review of the basic data and to help an evaluator become oriented with the application contents, the display of information should be unambiguous and transparent throughout the CTD.

If additional or supplementary data are submitted, the module(s) should be identified, and numbering should follow from the original documentation.

The applicant should submit all the sections of the modules. Justification for the non-applicable sections should be provided under the relevant headings.

Acronyms and abbreviations should be defined the first time they are used in each module. An application not submitted in the appropriate format, incomplete or illegible will be rejected.

2 Documentation

The review templates (QOS, QIS, BTIF and biowaiver forms) should be submitted in Microsoft Word.

All other sections of the dossier should be in text-selectable PDF format.

3 Organising documents

The organisation of modules should be consistent with the structure described in this guideline in the relevant tables below.

Table 1: Module 1

Module 1			
	1.1		
	1.2	1.2.1	
		1.2.2	
		1.2.3	
		1.2.4	
		1.2.5	
		1.2.6	
		1.2.7	
		1.2.8	
		1.2.9	
		1.2.10	
	1.3	1.3.1	
		1.3.2	
		1.3.3	
	1.4	1.4.1	
		1.4.2	
		1.4.3	
	1.5	1.5.1	
		1.5.2	1.5.2.1
			1.5.2.2
			1.5.2.3
	1.6	1.6.1	
		1.6.2	
	1.7	1.7.1	
		1.7.2	
		1.7.3	
		1.7.4	
	1.8		
	1.9		



	1.10		
	1.11		
	1.12		
	1.13	1.13.1	
		1.13.2	
	1.14		
	1.15	1.15.1	
		1.15.2	

Documents rolled up to this level are not considered appropriate
One document may be submitted at this level

TABLE 2: Module 2 (Electronic submissions)

Module 2		TOC should be hyperlinked	
	2.2		
	2.3 (Note 1)	Introduction	
		2.3.S Note 2	2.3.S.1
			2.3.S.2
			2.3.S.3
			2.3.S.4
			2.3.S.5
			2.3.S.6
			2.3.S.7
		2.3.P Note 3	2.3.P.1
			2.3.P.2
			2.3.P.3
			2.3.P.4
			2.3.P.5
			2.3.P.6
			2.3.P.7
			2.3.P.8
		2.3.A	2.3.A.1
			2.3.A.2
			2.3.A.3
		2.3.R	
	2.4		
	2.5		
	2.6	2.6.1	
		2.6.2	
		2.6.3	
		2.6.4	
		2.6.5	
		2.6.6	
		2.6.7	
	2.7	2.7.1	
		2.7.2	
		2.7.3 Note 4	
		2.7.4	

Key	
Documents rolled up to this level are not considered appropriate	
One document may be submitted at this level	
One or multiple documents can be submitted at this level	
Documents may not be submitted at this level for electronic submissions (documents may be written at this level but must be submitted at the higher level)	
Note 1: Optionality of granularity for the Quality Overall Summary is provided in order to accommodate different levels of complexity of products. The applicant can choose the level at which the QOS is managed.	
Note 2: One document should be submitted for each drug substance	
Note 3: For a drug product supplied with reconstitution diluent(s), the information on the diluent(s) should be provided in a separate part "p" document	
Note 4: One document for each indication should be submitted, although closely related indications can be within a single document	



TABLE 3: Module 3 (Electronic submissions)

Once a granularity option is chosen, continue with that option during the application's lifecycle.

Module 3 Note 1	3.2	TOC should be hyperlinked			Key
		3.2.S Note 2	3.2.S.1	3.2.S.1.1	Documents rolled up to this level are not considered appropriate
				3.2.S.1.2	One or multiple documents can be submitted at this level
				3.2.S.1.3	Documents may not be submitted at this level for electronic submissions. (documents may be written at this level but must be submitted at the higher level)
			3.2.S.2	3.2.S.2.1	
				3.2.S.2.2	
				3.2.S.2.3	
				3.2.S.2.4	
				3.2.S.2.5	
				3.2.S.2.6	
			3.2.S.3	3.2.S.3.1	
				3.2.S.3.2	
			3.2.S.4 Note 3	3.2.S.4.1	
				3.2.S.4.2	
				3.2.S.4.3	
				3.2.S.4.4	
				3.2.S.4.5	
				3.2.S.5	
				3.2.S.6	
			3.2.S.7	3.2.S.7.1	
				3.2.S.7.2	
				3.2.S.7.3	
		3.2.P Note 4	3.2.P.1		
			3.2.P.2	3.2.P.2.1 Note 5	
				3.2.P.2.2 Note 5	
				3.2.P.2.3	
				3.2.P.2.4	
				3.2.P.2.5	
				3.2.P.2.6	
			3.2.P.3	3.2.P.3.1	
				3.2.P.3.2	
				3.2.P.3.3	
				3.2.P.3.4	
				3.2.P.3.5	
			3.2.P.4	3.2.P.4.1	
				3.2.P.4.2	
				3.2.P.4.3	
				3.2.P.4.4	
				3.2.P.4.5	
				3.2.P.4.6	
			3.2.P.5 Note 3	3.2.P.5.1	
				3.2.P.5.2	
				3.2.P.5.3	
				3.2.P.5.4	
				3.2.P.5.5	

Note 1: In choosing the level of granularity for this Module, the applicant should consider that, when relevant information is changed at any point in the product's lifecycle, replacements of complete documents/files should be provided in the electronic submission.

Note 2: For a drug product containing more than one drug substance, the information requested for part "S" should be provided in its entirety for each drug substance.

Note 3: One or more control strategy summary documents may optionally be placed here.

Note 4: For a drug product supplied with reconstitution diluent(s), the information on the diluent(s) should be provided in a separate part "P", as appropriate.

Note 5: The lower level of each heading included in CTD-Q at this point is unlikely to contain individual documents or files.



				3.2.P.5.6
			3.2.P.6	
			3.2.P.7	
			3.2.P.8	3.2.P.8.1
				3.2.P.8.2
				3.2.P.8.3
		3.2.A	3.2.A.1	
			3.2.A.2	
			3.2.A.3	
		3.2.R	Note 6	
	3.3	One file per reference Note 7		

Note 6: Refer to regional guidelines.

Note 7: Literature References should be listed in the tables of contents.

Module 4	TOC should be hyperlinked					Key
	4.2	4.2.1	4.2.1.1	Studies Note 1		Documents rolled up to this level are not considered appropriate
			4.2.1.2	Studies Note 1		One or multiple documents can be submitted at this level
			4.2.1.3	Studies Note 1		
			4.2.1.4	Studies Note 1		
		4.2.2	4.2.2.1	Studies Note 1		Note 1: Typically, a single document should be provided for each study report included in Module 4. However, where the study report is large, (e.g., a carcinogenicity study), the applicant can choose to submit the report as more than one document. In this case, the text portion of the report should be one document and the appendices can be one or more documents. In choosing the level of granularity for these reports, the applicant should consider that, when relevant information is changed at any point in the product's lifecycle, replacements of complete documents/files should be provided.
			4.2.2.2	Studies Note 1		
			4.2.2.3	Studies Note 1		
			4.2.2.4	Studies Note 1		
			4.2.2.5	Studies Note 1		
			4.2.2.6	Studies Note 1		
			4.2.2.7	Studies Note 1		
		4.2.3	4.2.3.1	Studies Note 1		Note 2: Literature References should be listed in the tables of contents.
			4.2.3.2	Studies Note 1		
			4.2.3.3	4.2.3.3.1	Studies Note 1	
				4.2.3.3.2	Studies Note 1	
			4.2.3.4	4.2.3.4.1	Studies Note 1	
				4.2.3.4.2	Studies Note 1	
				4.2.3.4.3	Studies Note 1	
			4.2.3.5	4.2.3.5.1	Studies Note 1	
				4.2.3.5.2	Studies Note 1	
				4.2.3.5.3	Studies Note 1	
				4.2.3.5.4	Studies Note 1	
			4.2.3.6	Studies Note 1		
			4.2.3.7	4.2.3.7.1	Studies Note 1	
				4.2.3.7.2	Studies Note 1	
				4.2.3.7.3	Studies Note 1	
				4.2.3.7.4	Studies Note 1	
				4.2.3.7.5	Studies Note 1	
				4.2.3.7.6	Studies Note 1	

			4.2.3.7.7	Studies ^{Note 1}
4.3	One file per reference ^{Note 2}			

TABLE 4: Module 4 (Electronic submissions)

TABLE 5: Module 5 (Electronic submissions)

Module 5	TOC should be hyperlinked			
	5.2			
	5.3	5.3.1	5.3.1.1	Studies ^{Note 1}
			5.3.1.2	Studies ^{Note 1}
			5.3.1.3	Studies ^{Note 1}
			5.3.1.4	Studies ^{Note 1}
		5.3.2	5.3.2.1	Studies ^{Note 1}
			5.3.2.2	Studies ^{Note 1}
			5.3.2.3	Studies ^{Note 1}
		5.3.3	5.3.3.1	Studies ^{Note 1}
			5.3.3.2	Studies ^{Note 1}
			5.3.3.3	Studies ^{Note 1}
			5.3.3.4	Studies ^{Note 1}
			5.3.3.5	Studies ^{Note 1}
		5.3.4	5.3.4.1	Studies ^{Note 1}
			5.3.4.2	Studies ^{Note 1}
		5.3.5 Note 2	5.3.5.1	Studies ^{Note 1}
			5.3.5.2	Studies ^{Note 1}
			5.3.5.3	Studies ^{Note 1}
	5.3.5.4		Studies ^{Note 1}	
	5.3.6			
	5.3.7	Studies ^{Note 1}		
	5.4	One file per reference Note 3		

Key
Documents rolled up to this level are not considered appropriate
One document can be submitted at this level
One or multiple documents can be submitted at this level

Note 1: The applicants should ordinarily provide the study reports as multiple documents (a synopsis, a main body of the study report and appropriate appendices).

Appendices should be organized in accordance with the ICH E3 guideline, which describes the content and format of the clinical study report. In choosing the level of granularity for reports the applicant should consider that, when relevant information is changed at any point in the product's lifecycle, replacements of complete documents/files should be provided.

Note 2: For applications in support of more than one indication, this section should be repeated for each indication.

Note 3: Literature References should be listed in the tables of content.





4 Pagination

Page numbering should be at the document level and not at the module level. (The entire submission should never be numbered consecutively by page.) In general, all documents should have page numbers. Since the page numbering is at the document level, there should only be one set of page numbers for each document.

Cross-referencing to documents should be made by referring to the CTD module, , and page number (for example: "*see Module 3.2.P.4.3 Method validation, p 23*").

Documents must be legible, margin space must be sufficient so that no information is not obscured.

5 Paper size

Standard A4 paper should be used for all submissions. Text and tables should be prepared using margins that allow the document to be printed on A4 paper.

6 Fonts

Font sizes for text and tables should be of a style and size that are large enough to be easily legible, even when provided electronically. *Arial / Times New Roman 12 point* font is preferred for narrative text. The figures, tables and photos should be clearly legible.



7. Same/ Separate Applications

Tablets/Capsules/Suppositories/Lozenges	Application	
	Single	Separate
Different pack-sizes of the same strength and formulation	X	
Different strengths and/or formulations		X
Co-packaged products	X	
Components of a kit.		X
Syrups/Liquids/Solutions (non parenterals)/Creams/Ointments		
Different container sizes of the same strength and formulation	X	
Same container size of different strengths and/or formulations		X
Products with the same strength and formulation but with different colours and/or flavours		X
Ampoules, Vials and Large Volume Parenterals		
Ampoules containing identical solutions of the same strength but of different volumes (i.e. resulting in different total doses).		X
Ampoules containing solutions of different strengths		X
Ampoules and/or single dose vials containing dry powder, crystals etc, of different mass		X
Ampoules and single dose vials containing the same respective masses of dry powder, crystals etc, will require separate applications		X
Ampoules, single dose vials, as well as disposable syringes and cartridges containing identical solutions of the same strength and same volume of liquid		X
Dental cartridges containing fluids of different volumes	X	
Ampoules containing "water for injection", but of different volume	X	
Special ampoules of dry powder and "water for injections" contained in the same unit, but intended for mixing at the time of injection	X	
Ampoules containing identical solutions of different volumes used only as a diluent in the reconstitution of a preparation for parenteral use		X
Multi-dose vials of the same strength and formulation in different volumes		X
Multi-dose vials and a single dose ampoule of the same formulation		X
Multi-dose vials containing dry powder of different mass and the same formulation, and having the same concentration when reconstituted	X	
A container of diluent to be used with any preparation in (iii), (iv) or (xii) will require one application provided that the diluent is also fully described in the dossier together with the product; An ampoule of diluent to be used with any biological preparation	X	
Infusion solutions of the different volumes and of the same formulation, which are packed in containers of exactly the same type of material		X
Infusion solutions of same volumes and of the same formulation, which are packed in containers made of different types of materials		X
A preparation, packed in plastic containers and intended also to be marketed in glass containers containing the same volume and the same formulation, it will require one application provided the following data are submitted: - I. Characteristics of the rubber stopper; II. Specifications for the glass; III. A comprehensive manufacturing process with particular reference to the washing and sterilization cycles and apparatus used; IV. Data on particulate matter (contamination); V. Stability data with reference to the effect of the pH of the solution.	X	
Products with the same strength and formulation but with different colours		X



Applications containing the same active ingredient(s), and where additional indications are sought, where such new indications render the product in a different scheduling status, or different pharmacological classification or have any other restrictions imposed other than the original application		X
Different applicants/proprietary names for the same formula		
Same formula applied under different proprietary names		X
Same formula from different applicants		X



8. Payment for the application

- 10.0** The application fees applicable to each type of application should be paid as required. An application not accompanied by the appropriate fee will not be accepted. Reference should be made to the most recent statutory instrument for application fees.



PART B: MODULE 1

Module 1 should contain all administrative documents (e.g. application forms and certifications), labelling, general correspondence and annexes as needed. Documents should be organised in the order listed below.

Module 1.0 Cover Letter

Documentation		
1.	1.0	Cover Letter

Applicants should include a *Cover Letter on headed paper* with all applications. A signed cover letter should be placed at the beginning of Module 1.

Module 1.1 Comprehensive table of contents

Documentation		
1.	1.1	Comprehensive table of contents

Module 1 should include a comprehensive table of contents for the entire application. The comprehensive table of contents should include a complete list of all documents provided in the application by module.

In the table of contents, the location of each document should be identified by referring to the name of the document (section heading according to the CTD format e.g. 3.2.P.4.2). Page numbers should be used to facilitate location within documents.

Module 1.2 Application Information

Documentation		
1.	1.2.1	Application Form
2.	1.2.2	Letter of authorisation for communication on behalf of the applicant
3.	1.2.3	Electronic copy declaration
4.	1.2.4	Copy of certificate for a Vaccine Antigen Master File (VAMF)
5.	1.2.5	Copy of certificate for a Plasma Master File (PMF)
6.	1.2.6	Copy of certificate(s) of suitability of the European Pharmacopoeia (CEP)
7.	1.2.7	Confirmation of Prequalification (CPQ) of an API
8.	1.2.8	Letter of access from the APIMF holder, CEP holder or CPQ holder

1.2.1 Application form

Each application for registration of a medicine must be submitted in a format as set out in this guidelines

- (i) The application form should be completed in English.